TH03F Non-contact Forehead Thermometer

Intended use: The non-contact forehead thermometer is electronic thermometer using an infrared detector (thermopile detector) to detect body temperature from forehead center in people of all

Intended operator: Have eight years of education, no maximum.

Thank you for purchasing this Forehead thermometer. This thermometer is designed with an

advance infrared and ambient temperature compensation technology for accurate and fast temperature measurements. It also has a wide range mode to scan real time temperature. It is for home use, not meant to replace a visit to the doctor. Please also remember to compare the measurement result to your regular body temperature. Please consult with doctor if you have health concerns.

Operating Instructions

1 Always make sure the probe lens is clean without any damage, and the forehead is clean.

Marning: Choking from swallowing small parts and batteries by children or pets is possible, please keep small parts and batteries at places where children and pets can't reach.

- 2 Power on: Press the "ON/MEM" button.
- 3 Mode selection:
 - FOREHEAD Mode: The preset mode of thermometer is forehead. The thermometer is ready for use after the "HEAD" icon stops flashing and two beep sound.



Battery (on the rear cover) Probe

LCD

-Scan button

ON/MEM button

SURFACE Mode: In "Power On" mode, press and hold the "ON/MEM" button, then press the "SCAN" button, the ' a 'icon will replace "HEAD" icon in the LCD display.

4 Temperature taking:

Note: If there is any temperature difference between the places where the device is stored and where you are going to measure, subject and the device should stay in the same room for at least 15 minutes before measurement.



4.1 Measuring the FOREHEAD temperature: You can hold the thermometer within 1 cm from the central forehead (See Figure 1) and press the "SCAN" button to get the forehead measurement. The time consuming for measurement might be 1 second. After two short beeps are heard.

Note: Forehead temperature is displayed in Oral Mode. This thermometer is an adjusted mode thermometer that converts the forehead temperature to display its "Oral equivalent." (according to the result of the clinical evaluation to get the offset

4.2 Measuring temperature under SURFACE mode: When you press the "Scan" button, you will get the temperature immediately about 0.6 sec. If you keep pressing the scan button, the reading of measurement will update continuously.

Note: Surface mode shows the actual unadjusted temperatures, which is different from the forehead mode.

5 Switching between Celsius (°C) and Fahrenheit (°F):

To change the LCD from °C to °F: In "Power Off" mode, press and hold the "SCAN" button, then press the "ON/MEM" button for 3 seconds, icon "°C" will be switched to icon "°F". You can also use the same process to change the LCD display from "F to "C."

- 6 Memory Function: Press the "ON/MEM" button to see the temperature stored. This thermometer provides 25 sets memory for the body temperature. ** Please notice that only the "HEAD" function's reading will be recorded.
- 7 Power off: Device will automatically shut down after 1 minute pending to extend battery life. At next power on, it will go back to the default setting of "HEAD" temperature function



Holding the thermometer too long may cause a higher ambient temperature reading of the probe.

This could make the body temperature measurement lower than usual.

If the thermometer detects a temperature ≥37.5°C (or 99.5°F) under forehead mode, three short beep sound will follow one long beep sound to warn the user for potential fever.

Specifications:

Comply with ASTM E1965-98, EN ISO 80601-2-56, IEC/EN60601-1-2 (EMC), IEC/EN60601-1 (Safety) standards, ISO10993, RoHS.

Temperature measurement range: Forehead mode 34~42.2°C (93.2~108°F), Surface mode: -22~80°C (-7.6~176°F)

Accuracy: Forehead mode: ±0.2°C (0.4°F) within 35~42°C (95~107.6°F), ±0.3°C (0.5°F) for other range.

Surface mode: ±0.3°C (0.5°F) within 22~42.2°C (71.6~108°F).

others ±4% or ±2°C (4°F) whichever is greater.

Operating Range: 10~40°C (50°F ~104°F), 15%~85% RH

** Storage temperature range: It should be stored at room temperature between -20~+50°C, RH≤85%

Transportation temperature shall be less than 70°C. RH≤95%

Atmospheric pressure: 800~1013 hPa

Enclosure Rating: IP22

Dimensions: 79.1 x 39.0 19.3 mm Weight: 31.5 grams including battery

Battery life: around 3,000 continuous readings.

Expected Service Life: 4 years

The device should not submerge into any liquids and expose it to direct moisture.

There is no gender and age limitation for using infrared thermometer. This is not an AP or APG product.



The Probe Lens is the most delicate part of the thermometer. Use with care when cleaning the probe lens to avoid damage.

** The thermometer is NOT water-proof. Please keep the unit dry and away from any liquids.

a. Please use alcohol swabs or cotton swabs moistened with 70%~75% alcohol to clean the probe lens.

b. Allow the lens to fully dry for at least 1 minute.

c. Keep the unit dry and away from any liquids and direct sunlight.

d. Clean the probe and probe lens after each use to ensure an accurate reading and avoid cross contamination.

/ Important Notes:

- 1. Before the measurement, the subject should stay in a stable environment for 5mins and avoid the exercise, bath for 30mins.
- 2. Remember to keep the forehead area clean and away from sweat, cosmetics and scar while taking temperature.
- 3. During the measurement, please away from the direct sunshine and wind.
- 4. The "Clinical Bias" is -1.4 ~ -1.7°C.
- 5. The "Limits of Agreement" is 0.98.
- 6. The "Repeatability" is 0.20°C.

Changing the Battery: It is supplied with one lithium cell (CR2032x1pcs)









- ① Loosen the screw on the back housing to open the back housing. ② Use the screwdriver to flip out the battery, Insert a new battery under the metal hook and press the other side of the battery down until you hear a "click" sound. ③ Close the upper side and then close the bottom side.
- (4) Fasten the screw on the back housing.

Troubleshooting:

Error Message	Problem	Solution
- HEAD-	Device stabilization in process.	Wait until HEAD stops flashing.
 	Battery is low and no more measurements are possible.	Replace the battery.
Er 3	The ambient temperature is not within the range between 10°C and 40°C (50°F~104°F).	Allow the thermometer to rest in a room at least 15 minutes at room temperature: 10°C~40°C(50°F~104°F).
٤٠	Error 5~9, the system is not functioning properly.	Unload the battery, wait for 1 minute and repower it. If the message reappears, contact the retailer for service.
Н	Temperature taken is higher than 42.2°C (108.0°F) for forehead mode or 80°C (176°F) for surface mode.	For forehead mode, please stay in a stable environment for 5mins and avoid the exercise and bath for 30min, then make sure the probe lens is clean before take a new temperature
Lo	Temperature taken is lower than 34°C (93.2°F) for forehead mode or –22°C (-7.6°F) for surface mode.	measurement. 2) For surface mode, please select target within specifications. If a mal-function still exists, please contact the nearest retailer.
1888°F	Device can not be powered on to the ready stage.	Change with a new battery.

Warranty: 12 months

Manufacture Date: as the serial number (please open the battery cover, it is shown on the inside of the device.)

Ex.SN:E512A000001, the first "E" is External, the second number "5" is the last number of manufacture year, the third and the fourth number "12" is the manufacture month, the others is the serial number.

Note: The thermometer is calibrated at the time of manufacture. If you question calibration mode, the accuracy of temperature measurements or unexpected events at any time, please contact the dealers or nearest service address.

Please report to the manufacturer and the competent authority of the Member State in which you are established about any serious incident that has occurred in relation to this device. in CE XX A

Warning: No modification of this equipment is allowed.

BF type applied part Please read the instructions for use

Company Name? General Information: Address? Website?

Date of issue: 2020-06-08 Ref No : 062020



IMPORTER

Company Name?

Medical Technology Promedt Consulting GmbH Add: Altenhofstrasse 80, D-66386 St. Ingbert, Germany

Radiant Innovation Inc.

Tel: +886-3-5644185, Fax: +886-3-5644170, E-mail:mkt@radiantek.com.tw Add: 1F. No.3. Industrial East 9th Rd., Science-Based Industrial Park.

HsinChu, Taiwan Http://www.radiantek.com.tw

C E 1639	The CE mark and Notified Body Registration Numbers, the requirement of Annex II from Medical Device Directive 93/42/EEC are met.		Please do not dispose of the product in the household waste at the end of its useful life. Disposal can take place at appropriate collection points provided in your country.	EC REP	Authorized representative in the European community
$\overline{\mathbb{A}}$	Caution	i	Please read the instructions for use		Paper Recycling
***	Manufacturer	†	BF type applied part	IP22	Classification for water ingress and particulate matter.
M	To protect the environme	-	of empty batteries at your retail	store or at appropria	ate collection sites

Manufacturer's declaration-electromagnetic emissions

The TH0xyz series is intended for use in the electromagnetic environment (for home healthcare) specified below. The customer or the user of the TH0xyz series should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment – guidance (for home healthcare environment)
RF emissions CISPR 11	Group 1	The TH0xyz series uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The TH0xyz series is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

Manufacturer's declaration – electromagnetic immunity

The TH0xyz series is intended for use in the electromagnetic environment (for home healthcare) specified below. The customer or the user of the TH0xyz series should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance (for home healthcare environment)
Electrostatic discharge(ESD) IEC 61000-4-2	Contact: ±8 kV Air ±2 kV, ±4 kV, ±8 kV, ±15 kV	Contact: ±8 kV Air ±2 kV, ±4 kV, ±8 kV, ±15 kV	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%

Power frequency(50, 60 Hz) magnetic field IEC 61000-4-8		30 A/m 50 Hz and 60 Hz	The TH0xyz series power frequency magnetic fields should be at levels characteristic of a typical location in a typical home healthcare environment.
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Manufacturer's declaration – electromagnetic immunity

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Immunity test	IEC 60601 test level	Complianc e level	Electromagnetic environment – guidance (for home healthcare environment)		
Radiated RF IEC 61000-4-3	10 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz	10 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz	Recommended separation distance: $d = 1,2 \sqrt{P}$ $d = 1,2 \sqrt{P}$ 80MHz to 800 MHz $d = 2,3 \sqrt{P}$ 800MHz to 2,7 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, a should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol:		

NOTE1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the TH0xyz series is used exceeds the applicable RF compliance level above, the TH0xyz series should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the TH0xyz series.

Recommended separation distances between portable and mobile RF communications equipment and the TH0xyz series

The TH0xyz series is intended for use in an electromagnetic environment (for home healthcare) in which radiated RF disturbances are controlled. The customer or the user of the TH0xyz series can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the TH0xyz series as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter	Separation distance according to frequency of transmitter				
W	150 kHz to 80 MHz $d = 1,2 \ \sqrt{P}$	80 MHz to 800 MHz $d = 1,2 \sqrt{P}$	800 MHz to 2,7 GHz $d = 2,3 \sqrt{P}$		
0,01	N/A	0,12	0,23		
0,1	N/A	0,38	0,73		
1	N/A	1,2	2,3		
10	N/A	3,8	7,3		
100	N/A	12	23		

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Manufacturer's declaration-electromagnetic immunity Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment

The TH0xyz series is intended for use in the electromagnetic environment (for home healthcare) specified below. The customer or the user of the TH0xyz series should assure that it is used in such an environment.

Test frequency (MHz)	Band ^{a)} (MHz)	Service ^{a)}	Modulation ^{b)}	Maximum power (W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)	Compliance LEVEL (V/m) (for home healthcare)
385	380–390	TETRA 400	Pulse modulation b) 18 Hz	1,8	0,3	27	27
450	430–470	GMRS 460, FRS 460	FM c) ±5 kHz deviation 1 kHz sine	2	0,3	28	28

710			Pulse						
745	704–787	LTE Band 13,17	modulation b) 217 Hz	0,2	0,3	9	9		
780			217 112						
810		GSM 800/900,							
870	800–960	TETRA 800, iDEN 820,	Pulse modulation b) 18 Hz	2	0,3	28	28		
930		CDMA 850, LTE Band 5							
1720		GSM 1800; CDMA 1900; GSM							
1845	1700– 1990	1900-	Pulse modulation b) 217 Hz	2	0,3	28	28		
1970		1, 3, 4, 25; UMTS	1, 3, 4, 25;	4, 25;					
2450	2400– 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7		2	0,3	28	28		
5240		WLAN	Pulse						
5500	5100– 5800	802.11	modulation b)	0,2	0,3	9	9		
5785		a/n	217 Hz						

NOTE If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.

- a) For some services, only the uplink frequencies are included.
- b) The carrier shall be modulated using a 50 % duty cycle square wave signal.
- As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.